UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

May 30, 2008

DP Barcode:	D351172
MRID:	473676-01, -02, -03
Subject::	*Valvtect Marine Heavy Duty Premium Diesel with Bioguard Microbiocide*
Reg. No.	EPA REG. # 60061-REI
Document Type:	Product Chemistry Review
End-Use Product [X]	
Ingredients (PC Codes):	100801, 100802
CAS Numbers:	NA
Submitter:	Kop-Coat, Inc. .
Guidelines:	830.1550
Commodities:	Amended Confidential Statements of Formula
Reviewer::	Nancy G. Whyte Microbiologist, Special Assistant Product Science Branch
Organization:	Antimicrobials Division
Approver:	
Comment:	

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To: PM/PM Reviewer: Marshall Swindell/Martha Terry
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From: Nancy G. Whyte, Microbiologist/Special Assistant
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Applicant: Kop-Coat Inc.

Action code: A531

Due date: June 16, 2008

Product Formulation:

Active Ingredient(s):	**%/wt**
4-(2-Nitrobutyl) morpholine	15.%
4,4'-(2-ethyl-2-nitrotrimethylene) dimorpholine	2%
Total	100%

Background:

Kop-Coat Inc. has submitted an application for registration of a new end-use product, *ValvTect Marine Heavy Duty Premium Diesel with Bioguard Microbiocide*. This product is a multifunctional diesel fuel additive that prevents bacterial growth. The applicant provided a Confidential Statement of Formula (CSF) for the basic formulation (dated February 22, 2008). The product is produced by a non-integrated system. The registered product, [redacted] is the source of the two active ingredients.

Note: The applicant's letter to EPA (dated February 12, 2008) states that the product, *ValvTect Marine Heavy Duty Premium Diesel with Bioguard Microbiocide*, is substantially similar to the EPA-registered product, *ValvTect Marine Premium Diesel with Bioguard Additive* (EPA Reg. No. 60061-124).

Product ingredient source information may be entitled to confidential treatment

Findings:

Group A Requirements – *ValvTect Marine Heavy Duty Premium Diesel with Bioguard Microbiocide* (MRID 473676-01)

Group A product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.1800 (Analytical Method). See the "Recommendations" section of this report for deficiencies. See also Table A of this report.

Group B Requirements – Physical and Chemical Characteristics of *ValvTect Marine Heavy Duty Premium Diesel with BioGuard Micro-Biocide*: Color, Physical State, Odor, Flammability, pH, Viscosity and Relative Density (MRID 473676-02); and *ValvTect Marine Heavy Duty Premium Diesel with BioGuard MicroBiocide* (MRID 473676-03)

Group B product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.6314 (Oxidation/ Reduction; Chemical Incompatibility), OPPTS 830.6316 (Explodability), OPPTS 830.6317 (Storage Stability), OPPTS 830.6319 (Miscibility), OPPTS 830.6320 (Corrosion Characteristics), and OPPTS 830.6321 (Dielectric Breakdown Voltage). See the "Recommendations" section of this report for deficiencies. See also Table B of this report.

Good Laboratory Practices (GLP) statements were provided stating that the studies were conducted in compliance with the GLP standards as set forth in 40 CFR Part 160.

Confidential Statement of Formula

Certain information on the CSF must be revised, as noted in the Recommendations" section of this report.

Product Label

Certain information on the product label must be revised, as noted in the "Recommendations" section of this report.

Certain information on the product label could be improved, as noted in the "Recommendations" section of this report.

Recommendations:

To satisfy OPPTS 830.1800 (Analytical Methods) requirements, an analytical method must be provided for the two active ingredients in the product, as requested under OPPTS 830.1800(b).

To satisfy OPPTS 830.6314 (Oxidation/ Reduction; Chemical Incompatibility) requirements, a qualitative or quantitative assessment of oxidation or reduction potential of the product – for example, by testing conducted in accordance with OPPTS 830.6314(b)(2)(ii) – must be provided.

To satisfy OPPTS 830.6316 (Explodability) requirements, a statement or test data characterizing the thermal and impact explodability of the product must be provided.

To satisfy OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements, results for a minimum of 1 year from a GLP-compliant storage stability and corrosion characteristics study must be provided. Testing of the product is currently underway. Initial results were provided for storage stability. Storage and disposal information on the product label needs to be revised if product composition (or packaging) deteriorates over time.
Note: Only one of the two active ingredients, 4-(2-Nitrobutyl) morpholine, was tested at the initial interval.

To satisfy OPPTS 830.6319 (Miscibility) requirements, a statement or test data regarding the miscibility of the product with oil or other non-polar solvents must be provided.

To satisfy OPPTS 830.6321 (Dielectric Breakdown Voltage) requirements, a statement regarding the conductivity of the product and the potential of the product to be used on or in the vicinity of electrical equipment must be provided.

The following revisions must be made to the CSF:

- Under Item #10, identify the two active ingredients by name, directly beneath the active ingredient source, [redacted].

- Under Item #13b, identify the nominal concentration for each of the two active ingredients, placing the values in parentheses. These values should match those listed on the product label.

- Under Item #14a, identify the upper certified limit for each of the two active ingredients, placing the values in parentheses.

- Under Item #14b, identify the lower certified limit for each of the two active ingredients, placing the values in parentheses.

- Under Item #17, correct the total weight to read "10,000 lbs."

- The following revisions must be made to the product label:

  - Add the following "Flammability" statement (the flashpoint of the product is greater than 80°F and not over 150°F): "Combustible: Do not use or store near heat or open flame"

  -Add a "Pesticide Storage" section and provide instructions for storing and safeguarding the product, including instructions that specify what to do if the\ product leaks or spills from the container.

  -The following revisions to the product label are recommended:
  Under the "Precautionary Statements" section, change "eating drinking" to read "eating, drinking."

-Under the "If Inhaled" section of the "First Aid" section, change "then gives artificial respiration" to read "then **give** artificial respiration."

-Under the "First Aid" section, add a blank line to separate the "Note to Physician" statement from the statement beginning: "Have the product container ...."

-Under the "Pesticide Disposal" section, change "actually hazardous" to read "**acutely** hazardous."

-Under the "Container Disposal" section, change "toed authorities" to read "**local** authorities."

-Under the "seller warranty" section, change "ac contained" to read "**as** contained."

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [X]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system [ ]
- If "ME-TOO," specify EPA Reg. No. of existing product: 60061-124

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [ ]
Note: The product is not intended for food use.

c. None of the inert ingredients listed on the Confidential Statement of Formula appear in the Agency's inert database by the name listed (common or trade name). The CAS numbers are listed as "CAS mixtures". instead of the chemical name. Therefore, it is not possible to determine at this time if these ingredients have been approved for use in pesticides.

c. Physical state of product: *Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [ ] No [X]

Note: The CSF must be revised to identify the two active ingredients and the nominal concentration and upper and lower certified limits of each of the two active ingredients.

f. Active ingredient(s)	NC	LCL	UCL
4-(2-Nitrobutyl) morpholine	15%	---	---
4,4'-(2-Ethyl-2-nitrotrimethylene) dimorpholine	2%	---	---
[as listed on the product label]			
[redacted]	[redacted]		[redacted]
[as listed on the CSF]			

g. For products produced by an integrated formulation system:
- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II. PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [ ] No [X]

Note: The CSF must be revised to identify the two active ingredients and the nominal concentration and upper and lower certified limits of each of the two active ingredients.

b. The formula contains one of the following:

• 10% or more of a petroleum distillate:	Yes [X]	No [ ]
• 1.0% or more of methyl alcohol:	Yes [ ]	No [X]
• sodium nitrite at any level:	Yes [ ]	No [X]
• a toxic List 1 inert at any level:	Yes [ ]	No [X]
• arsenic in any form:	Yes [ ]	No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [X] No [ ] Not applicable [ ]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [X] Not applicable [ ]
Note: The following "Flammability" statement must be added to the product label because the flashpoint of the product is greater than 80°F and not over 150°F: "Combustible: Do not use or store near heat or open flame."

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [ ] No [X]
Note: A "Pesticide Storage" section and instructions for storing and safeguarding the product must be added to the product label.

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [ ]
Note: Storage stability studies are ongoing and have not been completed.

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	473676-01
830.1600 Description of Materials	A	473676-01
830.1620 Production Process[2]	NA	
830.1650 Formulation Process[3]	A	473676-01
830.1670 Formation of Impurities[4]	A	473676-01
830.1700 Preliminary Analysis[5]	*[Not required for a non-integrated formulation system.]*	
830.1750 Certified Limits[6]	A – Standard certified limits were proposed for the active ingredient source and the solvent. A – Non-standard certified limits were proposed for the detergent. An explanation of the basis for the non-standard certified limits was not provided, as requested under OPPTS 830.1750(e)(4). The non-standard certified limits (12.68-13.46%) appear to be acceptable because they fall within the standard certified limit range (12.42-13.72%). A – A non-standard upper certified limit was proposed for the combustion improver. An explanation of the basis for the non-standard upper certified limit was not provided, as requested under OPPTS 830.1750(e)(4). The non-standard upper certified limit (15.49%) appears to be acceptable as it is less than the standard upper certified limit (15.79%). A standard lower certified limit was proposed for the combustion improver. A – Non-standard certified limits were proposed for the lubricity improver. An explanation of the basis for the non-standard certified limits was not provided, as requested under OPPTS 830.1750(e)(4). The non-standard certified limits (0.68-0.76%) appear to be acceptable because they fall within the standard certified limit range (0.65-0.790.79%).	473676-01

Data Requirements	Acceptance of Information	MRID No.
	A – A signed certification statement was provided, as requested under OPPTS 830.1750(g).	
830.1800 Analytical Method[7]	G – An analytical method must be provided for the two active ingredients in the product, as requested under OPPTS 830.1800(b).	
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Conclusions:

1. The Confidential Statement of Formula for this product is unacceptable for registration until all the deficiencies noted above are corrected. Specifically, the Confidential Statement of Formula is unacceptable because:

   a. There are no certified limits provided on the Confidential Statement of Formula,
   b. The concentration of the registered product cited as a source was not provided in Box 10 of the same form.
   c. The information provided for the inert ingredients in the formulation is insufficient to determine if they are approved for use in pesticides. See the Comment in the section concerning the Confidential Statement of Formula **(I. c, Page 4)**

2. All the deficiencies in the data submitted which are noted in the **Findings** Section above must be addressed and appropriate data revisions or additional information provided to the Agency for review and acceptance.